K010202

1 of 2

16. PREMARKET NOTIFICATION 510(k) SUMMARY

Date: July 31, 2001

Device Names:
OWL Radiofrequency (RF) System, Model URF-2A
OWL Brain Lesion Kit
OWL Tasker Intracranial Electrode Kit
OWL Cordotomy Electrode Kit
OWL Thermistor Cordotomy Electrode Kit
OWL Gasserian Ganglion Kit
OWL Gasserian Ganglion Kit with straight and curved lesion electrodes
OWL Facet Rhizotomy Kit
OWL Facet Denervation Kits

Common Names:
Radiofrequency lesion generator
Radiofrequency lesion probes and kits

Manufacturer:
Diros Technology Inc.
965 Pape Ave.
Toronto, Ontario, Canada M4K 3V6
Tel. 416-421-9211. Fax 416-412-9212

Applicant:
Leslie W. Organ
1837 Kempton Rd.
Charleston, SC 29412
Tel. 843-762-4174. Fax 843-853-2630
e-mail organl@aol.com

Product Codes:
Radiofrequency lesion generator 882.4400 Class II
Radiofrequency lesion probe 882.4725 Class II
Electrode, depth 882.1330 Class II

Predicate Devices:
For Radiofrequency Lesion Generator
OWL Instruments URF-1 (preamendment)
Radionics, Inc. RF Lesion Generator RFG-3C (K901540)
For RF Lesion Probes and Kits
OWL Brain Lesion Electrode (preamendment)
OWL Cordotomy Electrode (preamendment)
OWL Gasserian Ganglion Kit (preamendment)
OWL Facet Rhizotomy Kit (preamendment)
Radionics TM Lesion Electrode (K991399)
Radionics Cordotomy Electrode Kit TCE (preamendment)

Radionics Cordotomy Electrode Kit RCK-2A (preamendment)
Radionics Trigeminal Neuralgia Kit TEW (preamendment)
Radionics Trigeminal Neuralgia Kit TIC (preamendment)
Radionics Spinal Rhizotomy Kit SRK (preamendment)
Radionics SMK Sluyter Cannula (K870028)
Radionics Sluyter-Mehta Cannula (K963577)
Radionics Disposable RF Cannula RFK-DB (K980430)
Baylis Medical Co. RF Cannula (K972846)
Mercury Medical Disposable RF Cannula (K000073)
For Brain Stimulation Electrodes
OWL Tasker Brain Stimulation Electrode (preamendment)

Product Description

The OWL Radiofrequency System, Model URF-2A, consists of an electronic device – RF lesion generator, stimulator, and impedance monitor – and a variety of RF probes through which the functions of the electronic device are implemented. The RF lesion generator fulfills the intended use of the URF-2A, the creation of a heat ablative lesion in a targeted area of the central or peripheral nervous system for functional neurosurgical procedures or for the relief of pain. Probe design and construction relate to the target site and the path through which the probe is inserted to reach the target. The stimulator section of the URF-2A is used to aid in the identification of the target site prior to lesion making by responses to electrical stimulation. Impedance measurement is most often used to provide confirmation of the adequacy of lesion size by the manner in which tissue impedance changes during and immediately after application of the lesion.

Intended Use

The OWL Radiofrequency System, Model URF-2A and associated lesion probes are indicated for use in lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies, or for radiofrequency heat lesion procedures for the relief of pain.

Performance Standards

No applicable performance standards have been issued under section 514 of the Food, Drug, and Cosmetic Act. Substantial equivalence is based solely on a comparison of materials, design, specifications, and principle of operation as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Leslie W. Organ, M.D., BASc, PEng
Vice President, Research and Development
Diros Technology, Inc.
1837 Kempton Road
Charleston, South Carolina 29412

OCT 31 2001

Re: K010202
Trade/Device Name: OWL Radiofrequency System, Model URF-2A, and Associated Radiofrequency Lesion Probes
Regulation Number: 882.4400, 882.4725, 882.1330
Regulation Name: Radiofrequency lesion generator
Radiofrequency lesion probe
Depth electrode
Regulatory Class: II
Product Code: GXD, GXI, GZL
Dated: July 31, 2001
Received: August 2, 2001

Dear Dr. Organ:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OCT 3 1 2001

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510(k) Number (if known): K010202

Device Name: OWL Radiofrequency System, Model URF-2A, and Associated Radiofrequency Lesion Probes

Indications For Use:

1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or

2. Radiofrequency heat lesion procedures for the relief of pain.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010202

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)